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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,380

02/14/2006

Susan Ashwell

101064-1P US

1041

44992 7590 09/10/2007
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EXAMINER

SHAMEEM, GOLAM M

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

09/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/568,380

Applicant(s)

ASHWELL ET AL.

Examiner

Golam M. M. Shameem, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 17-25 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/07/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

This application is a 371 of PCT/GB04/03473 08/12/2004 is acknowledged.

Status of Claims

Claims 1-27 are pending in the application.

Receipt is acknowledged of amendment / response filed on August 06, 2007 and that has been entered.

Claims 17-25 and 27 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

Information Disclosure Statement

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 08/07/2007, which has been entered in the file.

Response to Election/Restriction

In response to the restriction requirement, Applicants have elected Group I, which includes claims 1-16 and 26 drawn to compounds and compositions, and the elected species as set forth found in Example 4 on page 36 of the specification, is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)). Therefore, the requirement for restriction is still deemed sound and proper and is hereby maintained.

Applicants preserve their right to file a divisional on the non-elected subject matter.

Art Unit: 1626

As set forth in the restriction requirement and an election of a single compound (or set of compounds), the invention will encompass all compounds that fall within the scope of the claim is as follows:

A compound having the formula (I) wherein:

R¹ and R² and the N to which they are attached in combination form an optionally substituted heterocyclyl;

R⁴ is as claimed and

R⁵ is as claimed.

As a result of the election and the corresponding scope of the compound identified, claims 17-25 and 27 and the remaining subject matter of claims 1-16 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn subject matter of claims 17-25 and 27 is properly restricted as it differs materially in structure and in element from the elected subject matter supra so as to be patentably distinct there from.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a), which forms the basis for all obviousness rejections, set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 and 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Baxter *et al* (2001) and further in view of Parrish *et al* (2003). Applicant claims substituted thiophene compounds, compositions and their method of uses thereof.

Determination of the scope and content of the prior art (MPEP §2141.01)

Baxter *et al* and Parrish *et al* teach analogous compounds, compositions having similar therapeutic utilities to those of instantly claimed invention.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the claimed compounds and that of the references herein lies in the selection of different variable substitutions in core thiophene ring, such as having an alkyl (methyl) group substitution for R² or R⁵ [substituted C₁₋₆ alkyl] in the instantly claimed compounds instead of hydrogen for the same position in the prior art compounds [assuming R¹ and R⁴ are either hydrogen or alkyl, STN International, HCAPLUS database, RN 354811-66-8 and RN 507475-44-7, a copy is provided with this Office action].

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

It would have been *prima facie* obvious to one having ordinary skill in the art at the time of the invention was made since both Baxter *et al* and Parrish *et al* teach similar compounds and compositions which are generic to the claimed compounds. It is well established that the substitution of alkyl (such as, methyl) for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. *In re Wood*, 199 U.S.P.Q. 137 (C.C.P.A. 1978) and *In re Lohr*, 137 U.S.P.Q. 548, 549 (C.C.P.A. 1963). The disclosure of Baxter *et al* and Parrish *et al* that teach several combinations, which would easily place Applicants invention in possession of the public at the time of Applicants invention, was filed. Therefore, in the instant

Art Unit: 1626

case, one skilled in the chemical art would be motivated to choose to replace a hydrogen atom with a methyl group or *vice versa* in view of the known teaching of the art. The claimed compounds are so closely related structurally to the homologous compounds of the reference as to be structurally obvious therefore in the absence of any unobviousness or unexpected properties. Since the core thiophene ring of compound is not novel and the novelty (if there is any) belongs to the selection of different variable substitutions, a great caution should be exercised to determine the patentability of the claimed invention. Therefore, in looking at the instant claimed compounds as a whole, the claimed compounds and composition would have been suggested to one skilled in the art unless unobvious or unexpected results can be shown.

Objections

Claims 1-16 and 26 are objected to for containing non-elected subject matter. The claims should be amended to exclude non-elected subject matter and within the scope of elected compound.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golem Shamed, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Tuesday-Friday from 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone number for this Group is 571-273-8300.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

Golam M. M. Shameem, Ph.D.
Primary Examiner
Art Unit 1626,
Technology Center 1600

A handwritten signature in black ink, appearing to read "G. Shameem", with a stylized flourish at the end.

GOLAM M. M. SHAMEEM, PH.D
PRIMARY EXAMINER